

Poet®IQ 8500H Agent Gas Analyzer Operator's Manual



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Warranty

Workmanship & Materials

Criticare Systems, Inc. (CSI) warrants new equipment to be free from defects in workmanship and materials for a period of two (2) years from date of shipment under normal use and service. The following exceptions apply to this statement and the warranty period as indicated:

Internal Batteries: one (1) year
O2 Cells and CO2 Absorbers: six (6) months
Y Style SpO2 Sensors: six (6) months

CSI's obligation under this warranty is limited to repairing or replacing, at CSI's option, any part which upon CSI's examination proves defective.

EXCEPT AS DESCRIBED IN THE PARAGRAPH ABOVE, CSI MAKES NO WARRANTIES, EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

Exemptions

CSI's obligation or liability under this warranty does not include any transportation or other charges or liability for direct, indirect or consequential damages or delay resulting from the improper use or application of the product or the substitution upon it of parts or accessories not approved by CSI or repair by anyone other than a CSI authorized representative.

This warranty shall not extend to any instrument which has been subjected to misuse, negligence or accident; any instrument from which CSI's original serial number tag or product identification markings have been altered or removed; or any product of any other manufacturer.

Safety, Reliability & Performance

Criticare Systems, Inc., is not responsible for the effects on safety, reliability and performance of the 8500H Agent Gas Analyzer if: assembly operations, extensions, readjustments, modifications or repairs are carried out by persons other than those authorized by Criticare Systems, Inc., or

the 8500H Agent Gas Analyzer is not used in accordance with the instructions for use, or

the electrical installation of the relevant room does not comply with NFPA 70: National Electric Code or NFPA 99: Standard for Health Care Facilities (Outside the United States, the relevant room must comply with all electrical installation regulations mandated by the local and regional bodies of government).

In Case of Emergency Contact

CRITICARE SYSTEMS, INC.
N7 W22025 Johnson Drive
Waukesha, WI 53186
USA

Telephone: (262) 798-8282
Tech Support: (800) 458-2697
Orders: (800) 458-4615
Fax: (262) 798-8290

Internet: www.csiusa.com

Service Return Policy

Return Procedure

In the event that it becomes necessary to return a unit to Criticare Systems, Inc., the following procedure should be followed:

Obtain return authorization. Contact the CSI Service Department at 800-458-2697 to obtain a Customer Service Authorization (CSA) number. (Outside the US, call 001-262-798-8282.) The CSA number must appear on the outside of the shipping container. Return shipments will not be accepted if the CSA number is not clearly visible. Please provide the model number, serial number, and a brief description of the reason for return.

Freight policy. The customer is responsible for freight charges when equipment is shipped to CSI for service (this includes customs charges).

Loaner service. In the U.S. If it is necessary to provide a loaner unit to any U.S. customer, CSI will ship the unit within one (1) working day, if available, by secure transport means.

For units under warranty, a loaner unit (if required) will be made available upon request.

For unit out of warranty, in the event of a loaner unit being required after the product warranty has expired and no extended service contract is in place, a charge will be applied to the customer's account.

Loaner units must be returned to CSI at the customer's expense within one (1) week after receipt of the repaired goods. If the unit is not returned within that time, the customer will be invoiced for the full purchase price of the equipment.

Outside the U.S. No loaners are available from CSI internationally. Contact your local CSI representative.

EC Declaration of Conformity

**Poet® IQ 8500H
Agent Gas Analyzer**

To view the Declaration of Conformity, visit the Criticare website at www.csusa.com. A copy of the Declaration can also be faxed. Contact Criticare's customer service department at (262) 798-8282 to obtain a faxed copy of the Declaration.

**Representative in the
European Union**

MDSS GmbH
Schiffgraben 41
30175 Hannover
Germany

Section 1 — Introduction

Description

The 8500H agent gas analyzer measures real time concentrations of anesthetic agent gases. The device measures gases using a sidestream method. The primary module measures concentrations of CO₂, N₂O, and halogenated anesthetic agents. The device can also measure oxygen concentrations using a galvanic cell.

Intended Use

The 8500H analyzer is intended to be used with an approved host monitoring system with the appropriate software or software upgrades. Follow supplier's instructions for compatibility and operating instructions. The 8500H analyzer (with a host monitor) is designed to monitor physiological parameters of patients within clinical care settings. The 8500H analyzer with host monitor is intended to monitor concentrations of halothane, enflurane, isoflurane, sevoflurane, and desflurane during anesthetic surgery.

The user is responsible for the interpretation of the monitored data that is made available. It is intended that the user is a professional health care provider. Physiological data, system alarms, and patient data analysis are available to the care provider from the host monitor.

The analyzer is designed to be used with only one patient at a time.

Integrated CO₂ and Agent Gas Detector

The primary hardware module of the 8500H analyzer is an integrated CO₂/agent detector (bench). The integrated detector measures carbon dioxide (CO₂), nitrous oxide (N₂O), and five halogenated anesthetic agent gases using the same sample collection path and testing apparatus. The analyzer uses proprietary High IQ™ technology to identify and quantify agent gases. There are no moving parts, reducing size of the detector and enhancing reliability.

The 8500H analyzer uses the sidestream method of measuring CO₂ and anesthetic agent gases. Gas is drawn through a nasal cannula or endotracheal adapter. The gas sample enters the monitor from a sampling tube into a water trap, which removes water vapor and particulate matter from the gas sample. The gas then enters the CO₂ (agent) detector where it is analyzed.

Capnometry (Measurement of CO₂)

The analyzer measures CO₂ concentrations and sends data suitable for continuous waveform display. The analyzer also detects end-tidal and fractional Inspired CO₂ levels, sending the data to the monitor where it is displayed numerically. End-tidal CO₂ (EtCO₂) is defined as the maximum CO₂ concentration at the end of expiration. The analyzer measures the CO₂ concentration and the monitor displays the numerical value. The EtCO₂ value is updated continuously with each breath cycle. The amount of CO₂ in the gas mixture inhaled by the patient is the Fractional Inspired CO₂ (FICO₂).

The analyzer measures CO₂ using the principles of infrared absorption spectrometry. An unknown concentration of gas (CO₂) is calculated by comparing its absorption of infrared light to that of a known standard. The absorption of light is directly related to the concentration of the gas. As infrared light passes through the sample gas chamber, the light transmitted is converted to a voltage signal. The analyzer converts the voltage into CO₂ concentration data that can be expressed numerically or as waveforms by the monitor. The Beer's Law calculation is performed by the software of the external 8500H module.

Infrared analysis of the gas samples is done using Beer's Law. The formula for Beer's Law is as follows:

$$I = I_0 e^{-\varepsilon(\lambda)cd}$$

I Infrared value of measured sample.

***I*₀** Infrared value of light source.

e Exponential function.

***ε*(*λ*)** Extinction coefficient.

c Concentration of the gas sample.

d Distance measured through the sample.

Agent Gas Measurement The agent detector samples gas breathed by the patient through a sidestream circuit. It measures the concentrations of CO₂, N₂O, and halogenated anesthetic agents in the sampled gas. The detector uses far-infrared measurements to identify concentrations of halothane, enflurane, isoflurane, sevoflurane, desflurane anesthetic agents and their mixtures.

The analyzer uses the principles of infrared absorption spectrometry to measure anesthetic gases in the same manner as explained for CO₂ measurement. The integrated detector determines the concentrations of anesthetic gases and CO₂ by measuring the optical absorption of the sampled patient gas at a number of specific wavelengths in the medium to long-wave infrared region.

Conditions of Use The 8500H monitoring system has been calibrated with dry NIST-traceable calibration gases at room temperature and pressure (~ 21C, 740 mmHg). Given the small effect of water vapor on agent gas and CO₂ measurements and the system's built-in temperature and pressure measurements and compensations, this 8500H system method of gas analysis per EN 864 is best described as ATPS (Ambient Temperature and Pressure, Saturated; 21C, 750mmHg, 100% Humidity Saturated).

The 8500H monitoring system is suitable for sustained pressure (breathing circuit) monitoring environments and has been tested per Clause 102 (Sustained Pressure) of EN 864.

Stability of Accuracy The 8500H analyzer has an internal barometer and thermistor that allow compensation for changes over a range of temperature and atmospheric pressures. The analyzer complies with EN 864 and EN12598 standards for cyclical pressure.

Agent Accuracy of Measurement The accuracy of a single agent measurement is defined by the formula,

$$m - (0.04m + 0.1) \leq x \leq m + (0.04m + 0.1)$$

where “**m**” is equal to the measurement in percent and “**x**” is the tolerance range.

Example of 5% HAL measurement, calculating the high limit of the tolerance range.

$$(5\% \text{ HAL} \times 0.04_{\text{Reading}}) + 0.1\%_{\text{Absolute}} = 0.3\%$$

$$5\% \text{ HAL} + 0.3\%_{\text{Tolerance}} = 5.3\%$$

Final tolerance range is 4.7% to 5.3% HAL.

Oxygen (O₂) Measurement

The 8500H analyzer uses the sidestream method of measuring O₂. The gas is sampled from the same gas intake system used for the integrated CO₂/agent detector. The shared water trap removes moisture and particulate matter from the gas samples.

Method The gas sample is measured using a reactive oxygen cell. The oxygen sensor is a galvanic electrochemical cell that works by a process known as oxidation reduction.

Oxygen from the sampled gas comes in contact with a highly reactive metal, reacts with the metal and produces a current. As the oxygen reacts, this reactive metal is gradually being used up. Once the metal is used up, the cell is depleted and can no longer sense oxygen.

The cell generates a voltage output proportional to the amount of oxygen in the sampled gas. This oxygen cell has an internal thermistor and circuitry that adjusts the output voltage based on current temperature of the cell. A predictive circuit electronically speeds up the cell response necessary for breath by breath measurements. This voltage is then processed by the microprocessor and displayed to the user.

The relationship between gas concentration and pressure is calculated by the microprocessor. The numerical value displayed by the host monitor (O₂ Calculated) is generated using the following formula.

$$O_2 \text{ Calculated} = O_2 \text{ Measured} \times \frac{20.9}{O_2 \text{ Ambient}} \times \frac{P_C}{P_0}$$

The measured O₂ predictive value is multiplied by a fixed value derived from room pressure divided by room ambient oxygen levels. The measurement is further adjusted by multiplying the ratio of the pressure determined at calibration (P_C) with the current pressure (P₀).

There is a negligible effect on oxygen measurements due to humidity.

Conditions of Use	The oxygen monitoring feature is appropriate for measuring respiratory O ₂ concentrations in all patient populations. The oxygen monitor is suitable for use in breathing systems and with the use of inhalation anesthetic agents.
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Stability of Accuracy	The oxygen cell contains temperature correction circuitry. The oxygen sensor temperature is maintained at a nominal 40 degrees Celsius to maintain a consistent performance.
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Specifications

*For the 8500H Analyzer
when used with a host
monitor*

Capnometry (CO₂)

Method:	Sidestream; non-dispersive infrared
Range:	0-99 mmHg, 0 to 12.5%, 0 to 12.5 kPa, 0 to 99 Torr
Resolution:	1 mmHg, 0.1%, 0.1 kPa, 1 Torr
Accuracy:	±0.2% abs. or 4% of reading for breath rates up to 60 breaths/minute
Flow Rate:	100, 150, 200 ml/min, user selectable
Flow Tolerance:	±10%
Rise Time:	(10-90%) 350 milliseconds @ 150 ml/min
Response Time:	2.25 seconds
Time from Cold Stat:	1 minute to first waveforms; <20 minutes to full accuracy
Calibration:	Auto-calibrating, Manual Calibration
Units:	mmHg; Volume Percent; kPa; Torr
Display:	Inspired CO ₂ , Expired CO ₂ (End-Tidal) Numerical values, capnograph, and breath by breath EtCO ₂ bar graph.

CO₂ Respiration

Source:	Capnogram
Range:	1 to 100 breaths/minute
Resolution:	1 breath/minute
Accuracy:	± 2 breaths/minute or 2% of reading

Nitrous Oxide (N₂O)

Method:	Sidestream; non-dispersive infrared
Range:	0 to 99 volume percent
Resolution:	1%
Accuracy:	± (1.5% abs. + 4% of reading) for breath rates up to 60 breaths/minute
Identification Threshold:	5% (for single and mixed agents)
Rise Time:	(10-90%) 400 milliseconds
Response Time:	2.5 seconds
Calibration:	Auto-calibrating, Manual Calibration
Units:	Percent
Display:	Numerical Inspired N ₂ O, Expired N ₂ O; N ₂ O waveform

Halogenated Agents

Method:	Sidestream; non-dispersive infrared
Units:	Volume Percent
Resolution:	0.1 Volume Percent
Range:	Halothane; 0 to 10.0 vol. % Isoflurane; 0 to 10.0 vol. % Enflurane; 0 to 10.0 vol. % Desflurane; 0 to 20.0 vol. % Sevoflurane; 0 to 10.0 vol. %
Accuracy:	± (0.1% abs. + 4% of reading) for breath rates up to 60 breaths/minute
Identification Threshold:	Halothane; 0.2 vol. % Isoflurane; 0.3 vol. % Enflurane; 0.3 vol. % Desflurane; 0.3 vol. % Sevoflurane; 0.3 vol. %
Mixed Gas Threshold:	0.2 vol. % + 10% of total concentration
Primary Agent Identification:	User Selectable or Automatic
Mixed Agent Identification:	Automatic (secondary agent)
Rise Time:	450 msec. for (10-90%) at 150 ml/min
Response Time:	2.5 seconds
Warm-up Time:	1 minute to first waveforms < 20 minutes to full accuracy
Calibration:	Auto-calibrating, Manual Calibration
Auto Zeroing:	Occurs 30 to 60 minutes Duration 3.0 to 7.0 seconds
Display:	Primary agent inspired and expired numerical values, Primary agent waveform, Secondary (mixed) agent numerical values
Effect of Interfering Gases:	Ethyl alcohol: Negligible Metabolic ketones: Negligible Carbon dioxide: Negligible Nitrous oxide: Negligible Helium: Negligible Acetone: Negligible Ether: Contraindicated Cyclopropane: Contraindicated Methoxyflurane: Contraindicated

Oxygen Monitoring (O₂)

Units:	Percent
Display:	Inspired O ₂ , Expired O ₂ , Numerical values, waveform
Method:	Oxidation-reduction galvanic cell
Range:	0-100%
Resolution:	1%
Accuracy:	± 3 vol. % (0 - 90%) ± 4 vol. % (91- 100%) for breath rates up to 60 breaths/minute
Rise Time:	(0-90%) 600 milliseconds
Response Time:	1.5 seconds

Pneumatics

Flow rate:	100, 150, 200 ml/min, User Selectable
Occlusion Clearing:	Automatic
Filters:	WaterChek™ 2+
Sample Lines:	Cat. No. 625N, 8 foot
Pneumatic Sound Pressure:	45 dBa maximum @ 1 meter

Communications/Connections

Communication:	Async Serial (RX/TX); CANBUS
IBench Data Port:	DB-9 connector
Charger Port:	12.0VDC nominal, 1.0 Amp nominal

Mechanical/Electrical (8500H Analyzer)














Weight:	7.5 lbs; 3.4 kgs
Size:	4.20" (H) x 13.75" (W) x 10.75" (D) 10.7 cm (H) x 34.9 cm (W) x 27.3 cm (D)
Mechanical Shock Resistance:	Negligible affect up to 40G
Power:	6W peak, 3W typical
Voltage:	12 VDC Typical

Environmental (8500H Monitoring System)

Operating Temperature:	59° to 95°F, 15° to 35°C
Storage Temperature:	23° to 122°F, -5° to 50°C
Operating and Storage Humidity:	15% to 90%; non-condensing
Altitude:	-1000 ft. to 10,000 ft (-300 m to 3000 m)
Medical Device:	Class II Equipment (IIb EU)
Electrical Protection:	Class I Equipment
Degree of Protection:	Type CF, Defibrillator-Proof
Protection against ingress:	Ordinary; (Complies with the ingress protection test specified in IEC 601-2-27 ECG Safety Standard.)

All specifications are subject to change without notice.

Symbols

Symbol	Definition
	Refer to Operator's Manual for Information
	Shock Hazard
	European Community Mark of Approval
	Electrical Testing Laboratories (ETL) Mark
	Underwriters Laboratories Recognized Mark (external power supply)
	Dispose of unit and/or accessories following proper facility procedures or local laws.
	Technical Support Phone Number
	Type B Equipment
	Gas Sampling Connection
	Gas Scavenging Connection
	Signal connection to a host monitor
	Power Source
	Single use device only. Do not reuse.

Safety

Definitions for Warning and Caution symbols:



WARNING

Designates a possible dangerous situation. Non-observance may lead to death or the most severe injuries.



CAUTION

Designates a possible dangerous situation. Non-observance may lead to minor injuries or damage to the product.

Warnings



WARNING

- Read this manual entirely before attempting clinical use of the monitoring system.
- A possible explosion hazard exists! Do not use the monitoring system in the presence of flammable anesthetics.
- Cables, cords, and sampling lines may present a risk of entanglement or strangulation! Verify safe and proper positioning of these items after patient application.
- Unapproved modifications to the analyzer or host monitor may cause unexpected results and present a hazard to the patient.
- Risk of electrical shock! Do not remove cover. Refer servicing to qualified personnel.
- U.S. Federal law restricts this device to sale by or on the order of a physician.



Cautions



CAUTION

- Use the monitoring system only with recommended accessories! Use of unapproved accessories may cause inaccurate readings.
- Equipment accuracy may be affected at extreme temperatures.
- Do not store equipment at extreme temperature. Temperatures exceeding specified storage temperatures could damage the system.
- Do not press on the keys with surgical instruments or other tools. Sharp or hard objects could damage the keys. Use only your fingertips to press on the keys.
- Changes or modifications not expressly approved by Criticare Systems, Inc., may void the user's authority to operate the equipment and may also void the warranty.
- The AC power cord can be disconnected from the external power supply to serve as an AC disconnect.

Leakage Current	The monitoring system complies with leakage current limits required by medical safety standards for patient-connected devices. Standards include Underwriter's Laboratories (UL) 2601 and the International Electrotechnical Commission (IEC) 601-1, 2nd edition, 1988 Part 1. A hazard caused by the summation of leakage currents is possible, when several pieces of equipment are interconnected.
Voltage Fluctuations	When operated in the line voltage range specified in this manual any fluctuation will have a negligible effect. Very low line voltage will cause the monitoring system to revert to battery power. The monitor is designed with circuitry that will turn the device off before spurious readings can be caused by a low battery condition.
Software Error Related Hazard Mediation	Criticare Systems, Inc., has quality control practices and procedures in place to review potential hazards as they relate to software.
Potential Interference	This device has been successfully tested to IEC 601-1-2 specified levels for emissions of and resistance to electromagnetic energy fields. External disturbances which exceed these levels may cause operational issues with this device. Other devices which are sensitive to a lower level of emissions than those allowed by IEC 601-1-2 may experience operational issues when used in proximity to this device.

MAGNETIC FIELDS

Use of the device in an MRI environment may interfere with MRI image quality. Use of MRI may interfere with the device.

The gas module is not intended for use in an MRI environment.

RADIO FREQUENCY INTERFERENCE

The device conforms with IEC 1000-4-3 for radio frequency interference, and will operate with negligible adverse effects.

CONDUCTED TRANSIENTS

The device conforms with IEC 1000-4-4, and IEC 1000-4-5 for conducted transients, and will operate with negligible adverse effects.

X-RAY

The device will operate with negligible adverse effects in an x-ray environment. However, the device should not be placed directly in the x-ray beam, which could damage the internal electronics of the analyzer.

OTHER INTERFERENCE

There is a negligible adverse effect to the device from electrocautery and electrosurgery, infrared energy, and defibrillation.

Biocompatibility	All patient-contact or user-contact materials in this device and its accessories have passed ISO 10993-5, -10, & -11 biocompatibility tests or have been in use in clinical environments in large numbers over an extended period of time predating these standards.
Latex Content	All Criticare Systems, Inc., products, including the agent gas analyzer, the monitoring system and accessories, are free from latex in any location that may result in patient contact.
DEHP Content	All Criticare Systems, Inc., products currently shipping are free of DBP and DEHP in any areas that would be intended for patient contact with blood, mucous membranes, or continuous skin/tissue contact.

Section 2 — Controls and Connections

This section provides an overview of the monitoring system. The accessory connections and communication ports for connecting a host monitor to the 8500H analyzer are described. For control panels, switches, and displays refer to the host monitor manual.

Poet® IQ 8500H Gas Analyzer

Front Panel The Poet IQ 8500H agent gas analyzer is an external gas sampling module for use with an external host monitor. Sampling for the analyzer is conducted through its own sampling port located on the front panel. The gas intake manifold is designed to accept Criticare WaterChek® water traps.

The 8500H analyzer receives all its power from a host monitor. A green LED, located on the left side of the front panel, indicates that the analyzer module is receiving power from the host monitor.

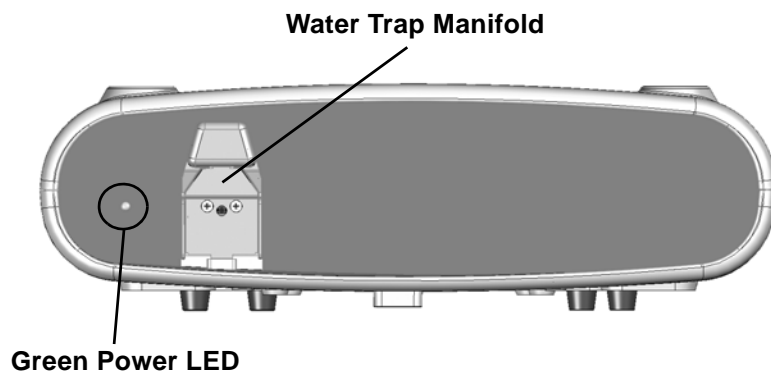


Figure 2-1: Poet IQ 8500H Front Panel

Rear Panel

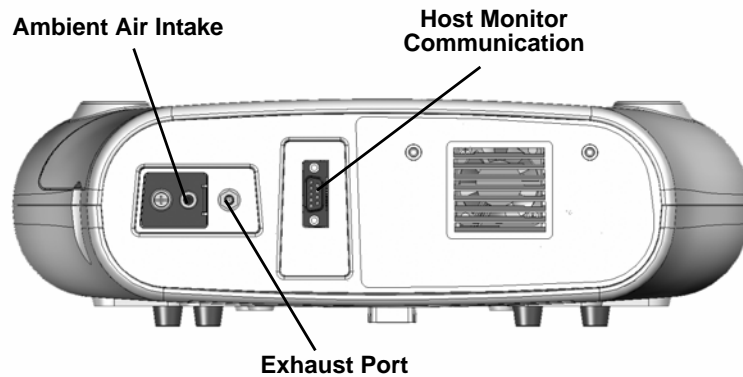


Figure 2-2: Rear Panel

AMBIENT AIR INTAKE

An ambient air intake port (located next to the exhaust port) is used for making zero gas concentration calibrations. Do not block or attach anything to the air intake port.

EXHAUST PORT

⚠ CAUTION ⚠

- Always use a scavenging line connected to the exhaust port and to the facility scavenging system.

An exhaust port is located on the rear panel. This port removes gases process by the 8500H analyzer.

HOST MONITOR PORT

The host monitor port is designated for the transfer of data between the 8500H analyzer and the host monitor. Power to the 8500H analyzer is supplied through the interface cable from the host monitor.

⚠ CAUTION ⚠

- The HOST MONITOR Port is reserved only for the transfer of data between the 8500H analyzer and the host monitor. This is not an RS-232 port and should not be used for printing or download applications.

The female DB-9 data port allows the 8500H analyzer to communicate data to and from the host monitor.

Section 3 — Setup Procedure

Monitor Setup

This section provides an overview of the setup procedures for using the 8500H analyzer.

The host monitor should be set up by the health care provider before using it on patients. If the monitor is new, preparations such as loading paper and batteries should be performed.

Auto-calibration and Warm Up

The agent gas analyzer may require a short warm up period and auto-calibration sequence similar to an internal capnometer. The message *AGT:WARMING* appears. The informational message *AGT:MANUAL* or *AGT:AUTOMATIC* may appear indicating that the monitor is in either manual or automatic primary agent identification mode.

Respiration waveforms, capnogram, and numerical breath rate will be available in one minute from powering the analyzer. The analyzer will reach full accuracy for agent concentrations in less than 20 minutes.

If the 8500H analyzer fails to auto-calibrate upon being plugged in the message *AGT:BAD CAL* or *AGT:CAL MISSING* may appear. If the 8500H analyzer continues to fail auto-calibration contact the Criticare Technical Service Department.

The 8500H oxygen monitoring module also requires an auto-calibration sequence and is performed at the same time as the agent detector calibration. If the O₂ module fails to auto-calibrate the message *O2: SENSOR* may appear.

Once auto-calibration is complete the host monitor will display values for monitored gases.

Primary Agent Selection

The primary agent for monitoring should be correctly entered depending on the host monitor. The analyzer has two modes of agent gas monitoring. Depending on the host monitor, the user may select a specific halogenated agent to be designated as the primary agent. The user may otherwise set the monitor to automatically detect and identify the current primary gas of a mixture.

WARNING

- Always confirm the primary agent selection before use. Incorrect primary agent setting may result in erroneous limit alarms. Alarm characteristics of the monitor are altered when automatic primary agent detection is activated.
- Never substitute a primary agent setting for a different halogenated agent, or any agent not listed! The agent detection is specific to the listed gases only.

 **WARNING** 

- The alarm *WRONG AGENT* may appear when the primary agent (that is manually selected by the physician) does not match the primary agent detected. Consult the instructions for your specific host monitor.
- The halogenated agent waveform and waveform label may automatically change to a different halogenated agent when automatic primary agent detection is used. If no primary agent is detected, dashes will appear in the waveform label, when automatic primary agent detection is used. Consult the instructions for your specific host monitor.

Flow Rate Setting The *Flow Rate* setting adjusts the amount of sample gas that is drawn in by the gas monitoring system. The analyzer has been calibrated to be functional at 100, 150, and 200 ml/min. Consult the instructions for your specific host monitor.

Zero Calibration Request A zero calibration request may be made from the host monitor. The user may initiate a manual zero calibration for the internal capnometer only. The zero calibration setting will not appear when using the 8500H analyzer.

Set a zero cal request from the host monitor to start a zero calibration. When the internal capnometer is activated the zero calibration will immediately begin for the capnometer and internal oxygen sensor if present. A zero cal message should appear momentarily.

The internal capnometer is auto-calibrated upon start up, on 24 hour intervals, and upon every 3° C of ambient temperature change. Manual calibration can be performed during transport or during changing environmental conditions. There is a temporary loss of CO₂ and O₂ monitoring data during zero calibration of the capnometer.

When the 8500H analyzer is connected zero calibration will begin immediately for the agent gas analyzer and the 8500H oxygen sensor. Since CO₂ levels are measured by the agent detector hardware there is no separate calibration for capnometry with the 8500H analyzer. The 8500H analyzer continuously auto-calibrates on intervals not greater than 40 minutes. Auto-calibrations will last approximately 5 seconds and may temporarily interrupt waveform display. No manual calibration of the 8500H analyzer is necessary during normal operation.

N₂O Compensation Since nitrous oxide has a similar infrared signature to that of CO₂, and it also affects infrared signature characteristics of CO₂, special care must be taken when measuring CO₂ while nitrous oxide is being used. There are two forms of N₂O compensation with the 8500H analyzer. N₂O compensation for the internal capnometer and the gas analyzer function independently and differently.

A manual form of N₂O compensation is provided with the settings for the internal capnometer. Since the capnometer does not measure the amount of N₂O present, the compensation is generalized for N₂O levels within a 40 to 80 percent range. This feature must be manually activated when N₂O is being used.

The 8500H agent gas analyzer uses a polychromatic infrared technology to measure N₂O and CO₂ levels independently. The measuring process used in the 8500H detector is inherently unaffected by CO₂ and N₂O mixtures. If the N₂O level exceeds its threshold for the detection limit, the monitoring system (when set) can accurately compensate for a range of N₂O concentrations.

Section 4 — Patient Monitoring

Introduction to Clinical Use

This section provides instructions for patient connections and monitoring. The caregiver is expected to be fully familiar with patient monitoring techniques and with the functions of the monitoring system before using it with a patient.

Before you Begin

Protect yourself and your patient. Read the precautions for each measured parameter that appears in this section.

These instructions describe the use of basic sampling devices and accessories that come with your monitoring system. An extended list of approved accessories can be found in the appendix of this manual.

The monitor should always be checked by the caregiver before use for actual patient monitoring. Perform the following procedure before using the monitor with a patient.

1. Confirm that the selected monitor is fully compatible with the gas analyzer.
2. Make sure that monitor has been fully charged before use. Check that the monitoring system's AC power cord is plugged in for long-term monitoring situations. Check the communications cable for secure connection to the monitor and analyzer.
3. Check the menus and default settings on the monitor to confirm that the monitor is set up correctly.
4. Examine the accessories for wear, damage, or contamination. Replace or disinfect the accessories as required.

WARNING

- All accessories connected to the gas analyzer and the patient monitor, must comply with applicable EN and IEC standards for such products.
- Substitution of recommended sensor and sampling accessories may cause inaccurate measurements and degrade patient safety, or may damage the gas analyzer and host monitor.

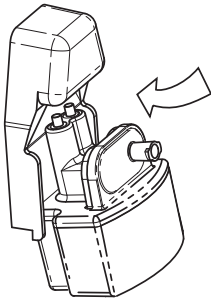
Gas Monitoring Safety The following instructions describe precautions and contraindications for gas monitoring. Use all safety procedures and protocols for anesthetic safety as designated by your health care facility.

 **WARNING** 

- Do not use this monitoring system in conjunction with highly flammable anesthetics such as cyclopropane or ether.
- The analyzer is not intended for monitoring gas mixtures containing methoxyflurane or halogenated hydrocarbons not specifically listed as a monitored gas.
- Environmental pollution of nitrous oxide and halogenated agents may cause accuracy errors. Always use anesthetic gas scavenging systems (AGSS) with the monitoring system.
- Infectious agents may be transferred between patients through the return of the analyzer's exhaust to the patient's breathing circuit.
- Infectious agents may be transferred between patients through contaminated masks and nasal cannulas. Change the sample device and sampling line before use with each new patient.
- Never attach intravenous tubes to gas sampling connections. Gas sampling lines may be inadvertently connected to intravascular fluid systems, allowing air into a blood vessel.
- Never place the gas analyzer or monitor inside an oxygen tent or any gas containment apparatus.
- Do not use anti-static or electrically conductive breathing tubes in the presence of electrocautery or electrosurgery equipment.

 **CAUTION** 

- Gas mixtures of oxygen or nitrous oxide with agents such as halothane, methoxyflurane or enflurane can be flammable. Do not operate the monitoring system if high ambient agent concentrations or anesthetic gas leaks are suspected.
- Always use a scavenging line connected to the exhaust port and to the facility scavenging system.

Water Trap Connections

The agent gas analyzer has a front mounted water trap. The trap slides out and can quickly be replaced if it becomes occluded. Use water trap Cat. No. 938F-NC WaterChek™2+ as indicated. The water trap has a fitting located at the top that connects into the trap receptacle (gas manifold) of the analyzer. The analyzer's gas sampling connection (from the water trap) will accept gas sampling lines using the male Luer style connections.

The attachment location of the sampling line is shown below with the water trap properly inserted. This sampling line, Cat. No. 625N, is used for agent gas monitoring with the Poet IQ 8500H agent gas analyzer. Use the gas sampling accessories only as directed.

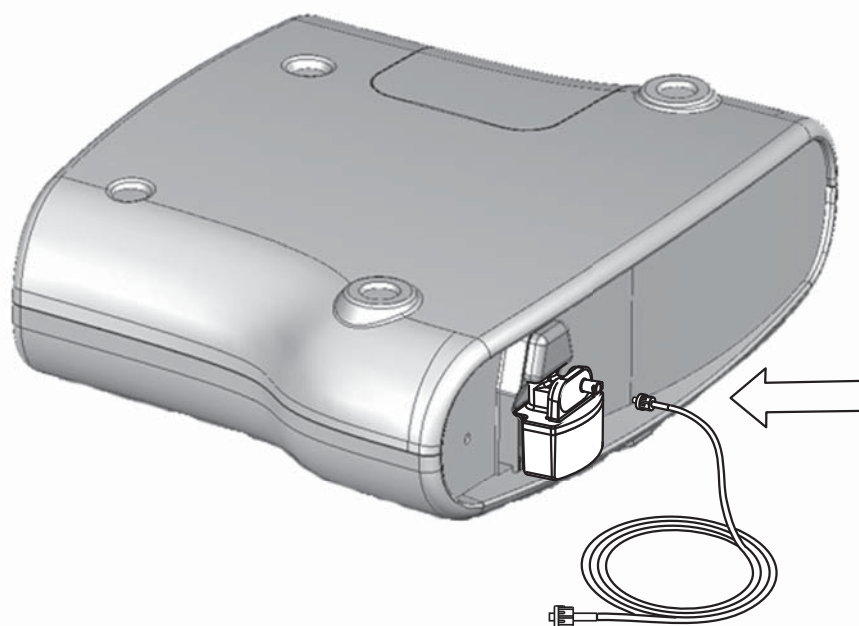


Figure 4-1: 8500H Sampling Line Connection

Startup and Calibration

Allow the 8500H analyzer and host monitoring system to warm up and auto-calibrate before use. It is necessary to have the water trap and sampling line attached so that the analyzer draws the correct air flow.

The 8500H analyzer will automatically begin an auto-calibration sequence when powered up. During calibration the monitor will display flat waveforms for gas concentrations. When the calibration and warm up sequence is over normal operation will begin.

Procedure for Gas Monitoring

The following description is provided for general monitoring of single or multiple gas conditions with the 8500H analyzer. Read the entire section for complete instructions for monitoring specific gases.

1. Check the *Flow Rate* setting of the host monitor.
2. If halogenated anesthetic gases are going to be used, verify the Primary Agent setting in the host monitor. The primary agent may be designated by the user or set to automatic identification.
3. Slide the WaterChek 2⁺ water trap (CAT No. 938F-NC) into the trap receptacle of the 8500H analyzer. Confirm that a cover is placed over the unused host receptacle if present.
4. Attach a scavenging line (CAT No. 655) to the rear exhaust port of the agent gas analyzer if anesthetic agents are being used. The exhaust port of the host monitor is not used when the agent gas analyzer is attached.
5. Attach a sample line (CAT. No. 625N) to the Luer connector located on the front of the WaterChek™ 2⁺ water trap.
6. Make sure there are no kinks or other obstructions in the line extending from the water trap.
7. Attach a patient sampling device to the sampling line. Use either a nasal cannula, mask or ventilation tube adapter.
8. Replace sampling devices, lines, and water traps if they become blocked.

WARNING

- Cables, cords and sampling lines may present a risk of entanglement or strangulation. Verify safe and proper positioning of these items after patient application.

NOTE: Nasal cannula, endotracheal adapters and sample lines are single patient use only.

NOTE: The water trap is intended to be used until filled or occluded. Once this occurs, discard the trap as it is not to be reused, and replace it with a new one. Do not attempt to drain and reuse the water trap.

Water trap capacity exceeds 8 hours under fully saturated conditions. A *REPLACE TRAP* alarm is generated when the trap is full.

Placement of Nasal Cannula If using the nasal cannula, position it directly under the patient's nose with the prongs extending into the nostrils. Slide the adjuster forward to close the loop around the head.

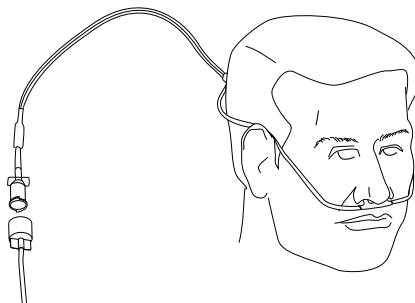
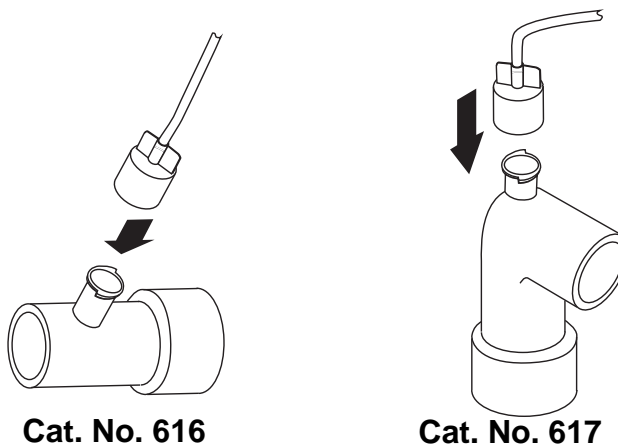


Figure 4-2: Nasal Cannula

Intubated Patients The agent gas analyzer can be used with intubated patients. Recommended sampling lines and water traps assemblies should be used. Sampling lines and water traps should be checked regularly.

Ventilation Circuit Adapters Two adapters for patient ventilation circuits are available. The adapters come with a Luer lock sampling port for use with the CAT. No. 625N sampling line (CAT. No. 616 Straight Tee Adapter and CAT. No. 617 Mask Elbow Adapter).

If additional adapters are required, Criticare recommends that they be no longer than two inches. Extending the sampling line will cause a delay in response time.



Cat. No. 616

Cat. No. 617

Figure 4-3: Ventilation Circuit Adapters

Occlusions The monitor displays a visual message *OCCLUSION* if the gas sampling system is blocked using either the internal capnometer or the gas analyzer. The message *CO2:OCCLUSION* always refers to the internal capnometer gas circuit of the host monitor. The message *AGT:OCCLUSION* always refers to the external 8500H analyzer gas circuit.

The 8500H analyzer will momentarily attempt to clear a blockage automatically drawing it into the collection basin of the water trap. If the sampling line or water trap becomes completely blocked, the sample line and/or the water trap should be replaced. There will be a brief interruption in gas monitoring during automatic occlusion clearing.

The monitor displays *NO EXHAUST* if the scavenging line is blocked on the gas analyzer.

Anesthetic Gas Monitoring

Allow the 8500H analyzer/host monitoring system to warm up and auto-calibrate before use. It is necessary to have the water trap and sampling line attached so that the 8500H analyzer draws the correct air flow.

Anesthetic Agent Identification and Quantification

The analyzer is an agent-specific monitor, which means that it is capable of simultaneously distinguishing between and quantifying various halogenated anesthetic agents. The halogenated agents which can be identified and simultaneously quantified at any given time are halothane, enflurane, isoflurane, desflurane, and sevoflurane.

Nitrous oxide and carbon dioxide are also identified and quantified and their effect in quantifying mixtures with the five halogenated agents is negligible. The presence of ethyl alcohol, metabolic ketones, helium, and acetone do not interfere with the agent detector and will not significantly affect accuracy. If any anesthetic agent other than those specified for monitoring is present, it won't be identified and may interfere with reported agent concentrations.

Primary Agent

If a waveform for a halogenated agent is displayed, it will be the primary agent that was manually set in the host monitor, or the primary agent as determined through automatic detection. The abbreviation for the agent will also appear above the expired value (the second column) in the gas numerical values box. The abbreviation for the agent will also appear at the beginning of the agent waveform channel.

The primary agent is the halogenated agent having the highest concentration during mixed gas conditions. The primary agent can be set to halothane, isoflurane, enflurane, desflurane, sevoflurane or automatic.

User Selected Primary Agent

When the monitor is manually set for a specific primary agent, the alarms will be keyed to the halogenated agent selected. The alarm limit levels will be the current primary alarm limits and should be manually updated if a new primary agent is selected. The current agent alarm limits will not change while monitoring unless done manually.

The *WRONG AGENT* alarm will be active and the monitor will continually check for an incorrect agent. If another halogenated agent exceeds the selected primary agent, a high priority alarm will occur. If the agent is being displayed in a waveform, the alarm message will appear in large red text in the waveform slot. If the *WRONG AGENT* alarm appears, immediately check the anesthetic delivery system for incorrect anesthetic gases.

When the user selects a specific halogenated agent as the primary, that agent will always be the agent displayed in the waveforms. A flat line will appear when the halogenated agent is not present.

**Automatic Primary
Agent Detection**

The primary agent is identified by the monitoring system as the agent with the highest current concentration. In mixed gas conditions the primary agent may change as the measured gas concentrations change. The waveform and waveform heading will also change to the new agent. When the monitor is set for automatic primary agent detection, the alarms will be adjusted to the current primary agent as defined at the host monitor. The alarm limits will be updated to those specified for whichever agent is currently at the higher concentration.

Secondary Agent Detection

When more than one halogenated agent is detected above its threshold limits the second highest halogenated agent is identified as a secondary agent. The *Mixed* message will be activated in the numerical parameter box for agent gas. Measurements for secondary agent expired and inspired values will appear. The secondary agent is automatically identified by its three letter abbreviation.

DURING AUTOMATIC PRIMARY AGENT SELECTION

If the primary agent concentration falls and/or is exceeded by another agent, the primary agent may become the secondary agent when automatic primary agent selection mode is used. The three letter agent name and values for the secondary agent may switch with the primary agent when the concentration of one agent exceeds another.

MIXED AGENT CONDITIONS

The message *MIXED AGENT* will appear as a medium level alarm whenever more than one halogenated agent is detected. The alarm is active whether automatic or manual primary agent selection is used. There are no concentration limit alarms associated with the secondary agent that is displayed. The presence of additional halogenated agents below the concentration of the secondary agent are not reported by the monitor.

**Agent Identification
Thresholds**

To identify an agent the concentration of the agent individually or in mixture must be above the identification threshold limit. A secondary agent is considered part of a mix if that agent is above its mix threshold limit.

Interfering Gases For Anesthetic Agents

The monitor will report small changes in agent concentrations when anesthetic agents and other gasses are used. Expected agent changes are provided here for the purpose of comparison

For Gas Mixtures of 2% Halothane

Agent	Agent Volume*	Change of Halothane
N ₂ O	60%	+0.1%
Halothane	4%	N/A
Enflurane	5%	+0.1%
Isoflurane	5%	-0.1%
Sevoflurane	5%	+0.1%
Desflurane‡	5%	+0.1%
Helium	50%	-0.1%
Ethanol	1%	0.0%
Isopropanol	1%	+0.1%
Acetone	1%	+0.1%
Methane	1%	0.0%
Metered does inhaler propellant	1%	0.0%
Xenon	80%	Not intended for use with Xenon

For Gas Mixtures of 2% Enflurane

Agent	Agent Volume*	Change of Enflurane
N ₂ O	60%	0.0%
Halothane	4%	+0.3%
Enflurane	5%	N/A
Isoflurane	5%	+0.1%
Sevoflurane	5%	-0.2%
Desflurane‡	5%	+0.1%
Helium	50%	+0.1%
Ethanol	1%	+0.1%
Isopropanol	1%	+0.1%
Acetone	1%	+0.1%
Methane	1%	0.0%
Metered does inhaler propellant	1%	+0.1%
Xenon	80%	Not intended for use with Xenon

* Gas mixtures balanced with Nitrogen.

‡ Presence of 15% Desflurane in a mixture with other halogenated gases will result in the display of 15% Desflurane readings or greater.

For Gas Mixtures of 2% Isoflurane

Agent	Agent Volume*	Change of Isoflurane
N ₂ O	60%	0.0%
Halothane	4%	-0.1%
Enflurane	5%	+0.6%
Isoflurane	5%	N/A
Sevoflurane	5%	+0.2%
Desflurane‡	5%	-0.2%
Helium	50%	0.0%
Ethanol	1%	+0.1%
Isopropanol	1%	+0.1%
Acetone	1%	+0.1%
Methane	1%	0.0%
Metered dose inhaler propellant	1%	+0.1%
Xenon	80%	Not intended for use with Xenon

For Gas Mixtures of 2% Sevoflurane

Agent	Agent Volume*	Change of Sevoflurane
N ₂ O	60%	0.0%
Halothane	4%	+0.3%
Enflurane	5%	+0.6%
Isoflurane	5%	+0.2%
Sevoflurane	5%	N/A
Desflurane‡	5%	-0.2%
Helium	50%	0.0%
Ethanol	1%	+0.1%
Isopropanol	1%	+0.1%
Acetone	1%	+0.1%
Methane	1%	0.0%
Metered dose inhaler propellant	1%	+0.1%
Xenon	80%	Not intended for use with Xenon

* Gas mixtures balanced with Nitrogen.

‡ Presence of 15% Desflurane in a mixture with other halogenated gases will result in the display of 15% Desflurane readings or greater.

For Gas Mixtures of 2% Desflurane

Agent	Agent Volume*	Change of Desflurane
N ₂ O	60%	0.0%
Halothane	4%	+0.5%
Enflurane	5%	+0.4%
Isoflurane	5%	+0.5%
Sevoflurane	5%	−0.1%
Desflurane‡	5%	N/A
Helium	50%	−0.1%
Ethanol	1%	0.0%
Isopropanol	1%	0.0%
Acetone	1%	0.0%
Methane	1%	−0.1%
Metered doses inhaler propellant	1%	+0.2%
Xenon	80%	Not intended for use with Xenon

For Gas Mixtures of 40% N₂O

Agent	Agent Volume*	Change of N ₂ O
N ₂ O	60%	N/A
Halothane	4%	+1.0%
Enflurane	5%	+1.2%
Isoflurane	5%	+1.3%
Sevoflurane	5%	+1.0%
Desflurane‡	5%	+1.2%
Helium	50%	+0.4%
Ethanol	1%	+0.8%
Isopropanol	1%	+1.5%
Acetone	1%	−0.1%
Methane	1%	+0.5%
Metered doses inhaler propellant	1%	+0.3%
Xenon	80%	Not intended for use with Xenon

* Gas mixtures balanced with Nitrogen.

‡ Presence of 15% Desflurane in a mixture with other halogenated gases will result in the display of 15% Desflurane readings or greater.

CO₂ Monitoring (Capnometry)

When a patient is connected, the monitor begins displaying the end-tidal and inspired CO₂ values in the parameter box. The capnogram, CO₂ waveform, if selected as a displayed waveform, will provide a graphic representation of the patient's respiration cycle.

A capnograph waveform is displayed using the agent detector data when the agent monitoring system is used. The waveform is generated by the capnometer when the host monitor is used by itself and has the internal feature installed.

The numerical respiration displayed value can be manually set to the capnogram source if desired. The host monitor may also generate a breath by breath bar chart in the waveform slots that can graphically indicate the relative strength of each breath. The graphical and numerical display of the capnogram will appear the same whether a host monitor's internal capnometer is used or the capnogram is drawn from the external gas 8500H analyzer module.

INTERFERING GASES FOR CO₂

The monitor will report small changes in CO₂ when anesthetic agents and other gasses are used. Expected CO₂ changes are provided here for the purpose of comparison.

For Gas Mixtures of 5% CO₂

Agent	Agent Volume*	Change of CO ₂
N ₂ O	60%	+0.2%
Halothane	4%	+0.1%
Enflurane	5%	+0.1%
Isoflurane	5%	+0.1%
Sevoflurane	5%	+0.2%
Desflurane‡	5%	0.0%
Helium	50%	0.0%
Ethanol	1%	+0.1%
Isopropanol	1%	0.0%
Acetone	1%	+0.1%
Methane	1%	0.0%
Metered dose inhaler propellant	1%	0.0%
Xenon	80%	Not intended for use with Xenon

* Gas mixtures balanced with Nitrogen.

‡ Presence of 15% Desflurane in a mixture with other halogenated gases will result in the display of 15% Desflurane readings or greater.

The 8500H agent gas analyzer automatically compensates for the presence N₂O. The table above indicates interference after this compensation has occurred.

Oxygen (O₂) Monitoring

When a patient is connected, the monitor begins displaying the expired and inspired O₂ numerical values in the parameter box. All procedures for patient setup, water traps, and occlusions apply to the O₂ measurement because the sample is taken from the same source as the CO₂ and the halogenated gases.

The parameters and procedures for oxygen monitoring are the same whether oxygen monitoring is performed by the internal oxygen sensor of the host monitor (if available) or by the external oxygen sensor of the 8500H analyzer.

When the 8500H analyzer is in operation, agent gas numerical values may appear in the box normally used for the display of oxygen concentrations. The oxygen numerical values may still appear in the same location inside the box.

INTERFERING GASES FOR O₂

The monitor reports small changes in O₂ when anesthetic agents and other gasses are used with oxygen. Expected O₂ changes are provided here for the purpose of comparison.

For Gas Mixtures of O₂

Agent	Agent Volume*	Change of O ₂
N ₂ O	60%	-0.1%
Halothane	4%	-0.2%
Enflurane	5%	-0.2%
Isoflurane	5%	-0.2%
Sevoflurane	5%	-0.2%
Desflurane‡	5%	-0.2%
Helium	50%	-0.3%
Ethanol	1%	-0.2%
Isopropanol	1%	+0.5%
Acetone	1%	+0.1%
Methane	1%	-0.1%
Metered dose inhaler propellant	1%	+0.2%
Xenon	80%	Not intended for use with Xenon

* Gas mixtures balanced with Nitrogen.

‡ Presence of 15% Desflurane in a mixture with other halogenated gases will result in the display of 15% Desflurane readings or greater.

Measurement Accuracy

The monitor will report small changes in agent readings when different concentrations are introduced. Expected agent changes are provided here for the purpose of comparison.

Measurement Accuracy at Different Concentrations

Agent	Agent Volume*	Change of Agent
CO ₂	0.0%	0.0%
	2.5%	0.0%
	5.0%	+0.2%
	10.0%	+0.1%
Halothane	0.5%	0.0%
	1.0%	0.0%
	4.0%	+0.2%
Enflurane	0.5%	0.0%
	1.0%	0.0%
	5.0%	+0.1%
Isoflurane	0.5%	0.0%
	1.0%	0.0%
	5.0%	+0.2%
Sevoflurane	0.5%	0.0%
	1.0%	-0.1%
	5.0%	-0.1%
Desflurane‡	5.0%	0.0%
	10.0%	+0.1%
	15.0%	-0.2%
N ₂ O	30.0%	+0.8%
	65.0%	-1.0%
O ₂	15.0%	+0.3%
	21.0%	+0.5%
	40.0%	-0.4%
	60.0%	+0.8%
	100.0%	-0.1%

* Gas mixtures balanced with Nitrogen.

‡ Presence of 15% Desflurane in a mixture with other halogenated gases will result in the display of 15% Desflurane readings or greater.

Measurement Accuracy for Gas Mixtures

The monitor will report small changes in agent concentrations when anesthetic agents and other gasses are used. Expected agent changes are provided here for the purpose of comparison.

Measurement Accuracy for Mixed Gases

Agent	Agent Volume*	Change of Agent
CO ₂	5.0%	0.0%
N ₂ O	30.0%	+0.1%
O ₂	40.0%	+0.4%
Halothane	2.0%	0.0%
CO ₂	5.0%	+0.1%
N ₂ O	30.0%	+0.8%
O ₂	40.0%	-0.4%
Enflurane	2.0%	-0.1%
CO ₂	5.0%	+0.1%
N ₂ O	30.0%	+1.0%
O ₂	40.0%	-0.3%
Isoflurane	2.0%	-0.1%
CO ₂	5.0%	+0.1%
N ₂ O	30.0%	+1.2%
O ₂	40.0%	-0.4%
Sevoflurane	2.0%	-0.1%
CO ₂	5.0%	-0.1%
N ₂ O	30.0%	+1.7%
O ₂	40.0%	-0.6%
Desflurane‡	8.0%	-0.3%

* Gas mixtures balanced with Nitrogen.

‡ Presence of 15% Desflurane in a mixture with other halogenated gases will result in the display of 15% Desflurane readings or greater.

Drift of Measurement Accuracy

The monitor will report small changes in agent concentrations over time. Expected agent changes are provided here for the purpose of comparison.

Drift of Measurement Accuracy

Agent	Agent Volume*	Change of Agent Over Time		
		0 hours	3 hours	6 hours
CO ₂	0.0%	0.0%	0.0%	0.0%
	2.5%	-0.1%	-0.1%	-0.1%
	5.0%	0.0%	-0.1%	-0.1%
	10.0%	0.0%	-0.1%	-0.1%
Halothane	0.5%	0.0%	0.0%	0.0%
	1.0%	0.0%	0.0%	0.0%
	4.0%	-0.1%	-0.1%	-0.1%
Enflurane	0.5%	0.0%	0.0%	0.0%
	1.0%	0.0%	0.0%	0.0%
	5.0%	+0.2%	+0.2%	+0.2%
Isoflurane	0.5%	0.0%	0.0%	0.0%
	1.0%	0.0%	0.0%	0.0%
	5.0%	+0.2%	+0.2%	+0.2%
Sevoflurane	0.0%	0.0%	0.0%	0.0%
	1.0%	-0.1%	0.0%	-0.1%
	5.0%	+0.2%	+0.2%	+0.2%
Desflurane‡	5.0%	0.0%	0.0%	0.0%
	10.0%	+0.1%	+0.2%	+0.2%
	15.0%	+0.2%	+0.2%	+0.2%
N ₂ O	30.0%	-0.2%	-0.8%	-0.3%
	65.0%	-0.8%	-0.8%	-0.4%
O ₂	15.0%	-0.2%	-0.2%	0.0%
	21.0%	-0.5%	-0.4%	0.0%
	40.0%	-0.6%	-0.8%	-1.0%
	60.0%	+0.1%	-0.4%	-0.4%
	100.0%	-0.4%	-0.2%	-1.0%

* Gas mixtures balanced with Nitrogen.

‡ Presence of 15% Desflurane in a mixture with other halogenated gases will result in the display of 15% Desflurane readings or greater.

Section 5 — Alarms and Messages

Alarm Description

The 8500H analyzer/host monitoring system provides both audible and visible alarm indicators to alert the operator of status alarms and physiological parameter alarms. All alarms conform to the requirements of the host monitor.

Alarm and Message List

Included here is a list of messages and warnings that may be generated by the 8500H analyzer. See the appropriate appendix for any host monitor specific messages.

Respiration Alarms and Messages

Alarms and messages for respiration may be generated by more than one sampling technology module.

	<u>Priority</u>	<u>Description</u>
LOW RESP	Medium	The respiration value has dropped below the value set at the host monitor.
HIGH RESP	Medium	The respiration value has exceeded the value set at the host monitor.

Capnometry (CO₂) Alarms and Messages

	<u>Priority</u>	<u>Description</u>
LOW ETCO ₂	Medium	The end-tidal CO ₂ value has dropped below the value set at the host monitor.
HIGH ETCO ₂	Medium	The end-tidal CO ₂ value has exceeded the value set at the host monitor.
LOW INCO ₂	Medium	The inspired CO ₂ value has dropped below the value set at the host monitor.
HIGH INCO ₂	Medium	The inspired CO ₂ value has exceeded the value set at the host monitor.

**Agent Gas
Alarms and Messages**

	<u>Priority</u>	<u>Description</u>
AGT:NO BREATH	High	No breath detected. Check patient for apnea. Check sampling device and adjust placement if necessary. May indicate a leak in the breathing circuit.
WRONG AGENT	High	The primary agent that the operator has selected does not match the highest concentration agent detected by the analyzer. Check the primary agent setting and the agent delivery system immediately. This alarm is not active when automatic primary agent detection is selected.
MIXED AGENT	Medium	More than one halogenated agent is present.
LOW INS AGENT	Medium	The inspired agent value has dropped below the value set at the host monitor.
HIGH INS AGENT	Medium	The inspired agent value has exceeded the value set at the host monitor.
LOW EXP AGENT	Medium	The expired agent value has dropped below the value set at the host monitor.
HIGH EXP AGENT	Medium	The expired agent value has exceeded the value set in the <i>ALARMS</i> menu.
LOW INS N2O	Medium	The inspired N ₂ O value has dropped below the value set at the host monitor.
HIGH INS N2O	Medium	The inspired N ₂ O value has exceeded the value set at the host monitor.
LOW EXP N2O	Medium	The expired N ₂ O value has dropped below the value set at the host monitor.
HIGH EXP N2O	Medium	The expired N ₂ O value has exceeded the value set at the host monitor.

	<u>Priority</u>	<u>Description</u>
AGT:OCCLUSION	Medium	The sampling line or water trap to the 8500H analyzer is completely blocked. The 8500H analyzer will attempt to clear the block by drawing the occlusion into the water trap. Replace sampling line as necessary.
AGT:INSERT TRAP	Medium	The water trap on the 8500H analyzer is not inserted. Trap is partially blocked, wrong type of trap, or defective. Replace the trap.
AGT: NO EXHAUST	Low	Scavenging line on the 8500H analyzer is blocked or the scavenging system is defective. Remove blockage or correct gas scavenging system.
AGT: BENCH FAIL	Low	The host monitor as detected a hardware failure in the 8500H analyzer. Contact the CSI Service Department.
AGT:IR FAIL	Low	The host monitor as detected a hardware failure in the 8500H analyzer. Contact the CSI Service Department.
AGT:PNEUMATICS	Low	The host monitor as detected a hardware failure in the 8500H analyzer. Contact the CSI Service Department.
AGT: BADCAL	Low	The 8500H analyzer was unable to calibrate the agent gas detector. Contact the CSI Service Department.
AGT: MISSING CAL	Low	The 8500H analyzer was unable to calibrate the agent gas detector. Contact the CSI Service Department.
AGT: WARMING	Informational	The 8500H analyzer has not attained full accuracy for agent concentrations.
AGT:MANUAL	Informational	The host monitor is set to manual identification of a selected primary agent. The <i>WRONG AGENT</i> warning may appear if the selected agent does not match the detected primary agent.
AGT:AUTOMATIC	Informational	The host monitor is set to automatic identification of the current primary agent.

**Oxygen Monitoring (O₂)
Alarms and Messages**

	<u>Priority</u>	<u>Description</u>
LOW ETO ₂	Medium	The expired O ₂ value has dropped below the value set at the host monitor.
HIGH ETO ₂	Medium	The expired O ₂ value has exceeded the value set at the host monitor.
LOW INO ₂	Medium	The inspired O ₂ value has dropped below the value set at the host monitor.
HIGH INO ₂	Medium	The inspired O ₂ value has exceeded the value set at the host monitor.
O ₂ :SENSOR	Low	The O ₂ cell inside the 8500H analyzer is expended and requires replacement. Contact Criticare Technical Service.

 CAUTION 

- Additional alarms and messages associated with other non-gas monitoring modules may appear on the screen of the host monitor.
- Additional host-generated alarms may alternate with any of the alarms listed in this section. At no time will any alarm, message or alert cause another message to not be displayed.

Section 6 — Maintenance

Cleaning and Disinfecting

WARNING

- Shock Hazard! The cable from the host monitor to the 8500H analyzer can be the power source. Unplug the cable from both the monitor and the analyzer before cleaning either device.
- Shock Hazard! Never immerse the agent gas analyzer or the host monitor.
- Additional cleaning and maintenance warnings and cautions are listed in the host monitor's literature.

Do not use abrasive cleaners on the host monitor or on any sensors or probes. Abrasive cleaners can damage the monitor, sensors, and probes.

The exterior surface of the analyzer may be wiped clean with alcohol and dried with a soft, dry cloth. It is best to use a cotton cloth to clean the analyzer.

Accidental Wetting

WARNING

- Shock Hazard! The host monitor with the 8500H analyzer is an AC powered system. Saturated electronic devices present a danger to anyone who handles them.

The action to be taken following accidental wetting of the equipment is as follows:

1. Turn the power off! Disconnect the AC power cord from the host monitor or from the external power supply.
2. If monitoring a patient, transfer the patient to another monitor as quickly as possible.
3. Use a clean, dry towel or cloth to remove the liquid from the device housing.
4. The analyzer or monitor should be inspected by a service technician as soon as possible.
5. If the internal mechanism is saturated, allow the liquid to drain out for 24 hours before shipping.
6. If liquid has entered the analyzer, it will need to be dried and cleaned internally. Full testing is required before the device can be used. Contact the CSI Service Department as soon as possible.

Time is critical! The longer any liquid remains in the device, the more damage it can do. It is important to service the analyzer immediately after any liquid is spilled into it.

Testing and Calibration

Refer to the *Poet® IQ 8500H Gas Analyzer Service Manual* for information about calibration and testing.

Annual Safety Tests

The analyzer should be electrically tested annually. Have a qualified service technician perform annually the safety testing listed in the 8500H service manual.

- Perform complete functional testing of the analyzer.
- Test the analyzer for electrical safety.

The functional tests to be performed as part of the annual safety tests are found in the *Poet® IQ 8500H Series Gas Analyzer Service Manual*. Annual safety tests include checking the flow rate and CO₂ absorber and verifying the agent gas calibration.

Service Checks

If the analyzer shows any signs of physical damage, return it to the CSI Service Department for repair.

Do not remove the cover. Refer all servicing to a qualified technician. Descriptions of these tests can be found in the *Poet® IQ 8500H Gas Analyzer Service Manual*. Some tests may require specialized equipment.

Maintenance Schedule

Every Patient	<ul style="list-style-type: none"> • Inspect the accessories and cables for damage and proper connection. • Change the gas sampling device, sampling line.
Every Week	<ul style="list-style-type: none"> • Change the water trap or as needed.
Every 3 Months	<ul style="list-style-type: none"> • Clean the exterior of the unit (or clean as needed). • Check the O₂ cell for drift. Calibrate if necessary.
Every Year	<ul style="list-style-type: none"> • Perform the annual safety tests. • Verify the agent gas calibration. • Change the O₂ cell. • Check the gas flow rate. • Check the CO₂ absorber and replace if necessary.

3 Month O₂ Drift Check

Equipment Needed The following equipment is required:

- WaterChek 2⁺ Water Trap (CAT 938F-NC)
- Sample Line (CAT 625N)
- Regulator Valve (CAT 623)
- Regulator Tube (CAT 613B)
- Calibration Gas, 80% O₂ with N₂ Balance (CAT 1547)

CAUTION

- Calibration kits contain compressed gas cylinders. Read and obey all instructions listed on the gas cylinder labels.
- Do not use if the calibration gas cylinder is beyond its expiration date.

O₂ Drift Check The O₂ function should be checked every three months to confirm accurate operation of the O₂ cell. The analyzer must be allowed to warm up prior to checking to ensure full accuracy. Allow the analyzer to run for up to ninety (90) minutes from the time of first ambient air readings before proceeding with the O₂ Drift Check.

NOTE: Analyzers coming from cold storage may require a longer warm up period.

If the analyzer does not pass the 3 month O₂ drift check, the cell must be calibrated. Refer to the *Poet® IQ 8500H Series Gas Analyzer Service Manual*.

1. Install a new CAT 938F-NC water trap on the 8500H analyzer and attach a CAT 625N sample line.
2. Allow the analyzer to read the ambient O₂ level for at least 30 seconds. The ambient O₂ level should be within ± 3 of 21%.
3. Establish a breath waveform by breathing across the opening of the sample line approximately 10 times.
4. Then supply the CAT 1547 80% O₂ canister directly to the sample line using a CAT 623 regulator valve and CAT 613B regulator tube.
5. Allow the gas to flow for at least 30 seconds. The 80% reading should be within ± 4 when using CAT 1547 calibration gas.

NOTE: The pressure in the O₂ canister must be sufficient that gas exhausts out of the CAT 613B regulator tube during testing.

Expendable Components

The internal oxygen cell (O₂ sensor) and carbon dioxide absorber will degrade over time. Replacement requires opening the analyzer's case and should be performed by a qualified service technician. See the *Poet® IQ 8500H Gas Analyzer Service Manual* for instructions.

Long-Term Storage

No special preparation is necessary for long term storage of the analyzer.

Disposal

At the end of its useful life, the analyzer and its accessories may be disposed of according to your institution's policies and procedures for disposal of patient-contact medical waste.

Alternately, the analyzer and its accessories may be returned to Criticare Systems, Inc. for safe disposal. The shipping address is:

Criticare Systems, Inc.
N7 W22025 Johnson Drive
Waukesha, WI 53186

Appendix A — Accessories

Gas Monitoring Accessories

Sampling Devices	Sample Lines (use with CAT 938F-NC; Box of 25)	625N
	Nasal Cannulas (Box of 10)	624
	Divided Nasal Cannulas (Box of 10)	628
	Endotracheal Adaptor, Straight (Box of 10).....	616
	Endotracheal Adaptor, Elbow (Box of 10)	617
	WaterChek™ 2+ Water Trap (Box of 30)	938F-NC
	Oxygen Sensor Cell	644
	CO ₂ Absorber	780
	Scavenging Exhaust Tube	655
	Scavenging Exhaust Tube (International)	655-I
Gas Testing Accessories	Cal Gas Cylinder (5% CO ₂ , Balance N ₂)	621
	Cal Gas Cylinder (10% CO ₂ , Balance N ₂)	622
	Cal Gas Cylinder (80% O ₂ , Balance N ₂).....	1547
	Regulator Valve	623
	Gas Regulator Tube	613B
	Breath Rate Simulator	1466
	8500A Serial Test Cable	P/N 90837A001
	Software O ₂ Calibration Tool.....	P/N 75667B001
	Cal Gas Aerosol (1% Isoflurane, 5% CO ₂ , 60% N ₂ O, Bal N ₂)	631
	Cal Gas Aerosol (1% Enflurane, 5% CO ₂ , 60% N ₂ O, Bal N ₂)	634
	Cal Gas Aerosol (1% Halothane, 5% CO ₂ , 60% N ₂ O, Bal N ₂)	635
	Cal Gas Aerosol (1% Sevoflurane, 5% CO ₂ , 60% N ₂ O, Bal N ₂)	1367
	Cal Gas Aerosol (4% Desflurane, 5% CO ₂ , 60% N ₂ O, Bal N ₂) ..	1366

Gas Testing Kits	O ₂ Gas Calibration Kit	1548
	80% O ₂ cylinder, 5% CO ₂ cylinder, regulator valve, plastic storage case	
	Simulator Kit 8500H	1549
	Breath Rate Simulator, serial test cable, software tool, sample line, regulator valve, 2 gas regulator tubes	
	Anesthetic Agent Verification Kit (5 Agent)	630
	One of each five aerosol agents: ISO, ENF, HAL, SEV, DES as described above, includes plastic regulators with tubing.	

Publications

Operator's Manuals	Poet IQ 8500H Operator's Manual CD - English	2215-CD
	Poet IQ 8500H Operator's Manual CD - Multi-Language.....	2216-CD
Service Manuals	Poet IQ 8500H Service Manual CD - English.....	2217-CD

Appendix B — Connecting with nCompass™ 8100H Series Patient Monitor

The 8500H agent gas analyzer connects to the nCompass™ 8100H Series patient monitor using a special communication/power cable. No external power supply is needed for the 8500H gas analyzer when connected to the 8100H host monitor. Power is supplied through the interface cable.

See the nCompass™ 8100H Series operator's manual for information about control panels, switches and screen displays.

Connecting to the 8100H Series Monitor

An 8100H to 8500H interface cable is all that is required to connect the agent gas analyzer to the 8100H host monitor. The cable is available in two lengths.

- 1 meter 8100H to 8500H interface cable (CAT 2041)
- 3 meter 8100H to 8500H interface cable (CAT 2042)

